DETAILED ACTION

Response to Interview

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action during the interview of 02/17/09 is persuasive and, therefore, the finality of that action is withdrawn.

Terminal Disclaimer

2. The terminal disclaimer filed on 07/31/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 11/089,207 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sepetka (US 2002/0169473) in view of Rosenthal (US 7,006,904) further in view of Kopecek (WO 98/01421).

5. Sepetka discloses a vaso-occlusive device implant, comprising:

an elongate, flexible, filamentous inner element (352); a non-metallic intermediate

element coaxially surrounding the inner element and in intimate contact therewith substantially along the length of the inner member (Para [0164] where the intermediate element is drug coating); and an outer element coaxially surrounding the intermediate element and in intimate contact therewith (354), the outer element defining a gap or opening through which the intermediate element is exposed and through which the intermediate element is capable of swelling (see for example Figs 62-64, 67, 68). The inner element comprises a microcoil (in the sense that micro is extremely small and therefore the limitation is not being given patentable weight). The outer element includes an open-wound, helically-coiled portion that defines the gap or opening through which the intermediate element is exposed. The proximal and distal end sections of the outer element are respectively attached to the distal and proximal ends of the inner element (although not necessarily fixedly attached, the coils are attached in the sense that are joined together as one element). Each of the proximal and distal end sections of the outer element includes a close- wound helical coil section (for example Fig. 67, 68).

6. Sepetka does not disclose the intermediate element being an expansile polymeric material that is a hydrogel. Sepetka does disclose that an intermediate element that is for providing drug delivery. However, Rosenthal teaches an expansile polymeric material element that is for providing drug delivery and consists essentially of hydrogel (C3:L37-39; C4:L6, 11). The hydrogel expands in response to change in temperature or pH (C 3: L33-41; C4:L10-14).

7. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in

their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention, namely a way of delivering a drug in a controlled manner via the use of hydrogel and a triggering mechanism. The use of hydrogel and a triggering mechanism allows the user to have full control over timing of the drug delivery thus preventing the drug from being released prematurely. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

8. The modified device would meet the limitation that the intermediate element, when expanded, extends though the openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments. Sepetka discloses the use of one coil as the outer element (Para [0164] *one or more secondary coils*) It is well known in the art that hydrogels can expand up to 600 times their original size. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01).

9. Sepetka modified by Rosenthal does not disclose not explicitly discloses that the hydrogel is *capable of* expanding at a controlled rate but does disclose that it is expanded by a change in temperature or pH. Kopecek also teaches the use of hydrogel to deliver drugs to the body. Kopecek further teaches that it is known in the art for hydrogels to swell at a chemically controlled rate when there is a change in pH. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the feature of controlled expansion of the hydrogel to further control the

delivery of the drug to the vessel and prevent trauma to the vessel that may be encountered from the hydrogel expanding too quickly or forcefully. Kopecek teaches that the feature is known in the art and a person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

10. Sepetka in view of Rosenthal does not disclose a coupling element attached to the proximal end of the inner element and to the proximal end of the outer element. It would have been well within the skill of the ordinary artisan to incorporate a coupling element at the proximal ends of the coils since it is old and well known to use coupling elements (i.e. welds, radiopaque markers, sutures) in medical implants having coaxially surrounding elements (i.e. embolic coils, stent-grafts, embolic filters). The common knowledge or well-known in the art statement is taken to be admitted prior art because applicant has failed to traverse the examiner's assertion of official notice

Response to Arguments

11. Applicant's arguments filed 07/31/08 have been fully considered but they are not persuasive. Applicant states that the coating is not an expansile element because Rosenthal discloses a balloon which would be the expansile element. It is irrelevant whether the prior art chooses to incorporate an additional expansile element (balloon) as applicant asserts. The coating is in and of itself an expansile element by the sheer fact that it expands. Although the prior art contains additional structure not required by Applicant's invention, it must be noted that the prior art does disclose the invention as claimed. Applicant goes on to explain that an expansile element would grow without the

assistance of a balloon. Examiner asserts that the expansile element being a coating does in fact grow without the assistance of the balloon. Although the prior art teaches the method of first expanding the balloon prior to expanding the hydrogel and releasing the drug, expanding the balloon is not required for the step of expanding the hydrogel to occur. As stated above in the rejection, Rosenthal does in fact disclose that the hydrogel can expand at a controlled rate by the use of a triggering mechanism, thus providing the advantage of preventing premature delivery of the drug.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731